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EXAMINER	
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1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

The amendment filed on September 21, 2010 has been received and entered. Pending claims 1 and 3-6 have been amended to correct grammatical and typographical errors.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1 and 3-6 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As discussed in the previous Office action, the claims are confusing because they are drawn to a set of purified peptides identified in Table 1 or Table 2. But, the peptides (peptide numbers) listed in these tables are not physical peptides. These tables do not represent a composition comprising these peptides, i.e., a composition comprising somewhere between 20 and all of these peptides. What is listed in Tables 1 and 2 are the molecular weights (masses) of a number of fragments, as measured by mass spectrometry, the results of mass spectrometry experiments. Applicants have not made compositions comprising the peptides of Table 1 or Table 2. Some of these molecular weights correspond to molecular ions, molecules that are the digestion products of human elastin digested with MMP12 (a.k.a., human macrophage elastase or matrix metalloproteinase 12). Other molecular weights correspond to molecules that are fragments of these digestion products, fragments produced by the ionization process in mass spec. Applicants have not produced compositions comprising the ionized fragments of the digestion products, and these numbers in the tables are data, not physical peptides or purified peptides. Further, it cannot be determined which peptides (as peptide numbers) correspond to the molecular ions and which correspond to their fragments. Clarification and appropriate are required.

Applicants assert that the peptide fragment masses listed in Tables 1 and 2 correspond to peptide fragments obtained by digesting elastin with MMP12 and subjecting the digestion to a reverse-phase preparation step before performing a MALDI-TOF mass spec analysis. Applicants assert that, via data mining techniques, based on the fragment masses, the known sequence of elastin and known mass spec algorithm software, one of skill in the art could identify the amino acid sequence of the polypeptide corresponding to each mass in Tables 1 and 2. Applicants refer to p. 45, lines 23-26, of the specification as a disclosure of their enzyme digestion and column chromatography procedures.

In reply, the rejection is not one of lack of enablement. The rejection is not that one skilled in the art, given the information available on elastin and MMP12, along with protein analysis software and mass spec analysis software, could not determine the amino acid sequences for elastin fragments corresponding to the various different masses listed in Tables 1 and 2. The rejection is that the claims are confusing and unclear, because the specification does not disclose the set of peptide fragments recited in the claims. Applicants have not made the claimed invention, as discussed previously and above. The cited portion of the spec states only that Tables 1 and 2 list the mass unit identities of elastin fragments resulting from MMP12 digestion and column chromatography. Based on the preceding paragraph on p. 45, it is not entirely clear what was done in the experiments. It appears that urine samples, from normal subjects and patients with COPD (chronic obstructive pulmonary disease), which contain elastin digested with MMP12, were fractionated by some type of size exclusion chromatography in which the gel had a molecular weight cut-off of 15 kDa. Each fraction was then fractioned by some type of cation exchange chromatography. Each fraction from the second column was fractionated by some type of reverse phase HPLC chromatography. Each fraction from the third column (there must be thousands of fractions at this point) is spotted on MALDI target plates by

a robot. Each target plate, having some number of spots, is then irradiated to produce a number of fragments from each spot. Each fragment from each spot is subjected to MALDI-TOF mass spec and then analyzed for its exact mass, quantity and isotope resolution. This procedure does not make a physical set of peptides that are fragments of elastin.

In view of the foregoing, the rejection of record is maintained.

Claim Rejections - 35 USC § 102

In view of Applicants' explanations that the enzyme of Kucich et al. (WO 91/18290 A1), human neutrophil elastase, is a different enzyme from MMP12, which is human macrophage elastase, this rejection is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSANNE KOSSON whose telephone number is (571)272-2923. The examiner can normally be reached on Mon., Tues., Fri., 8:30-6:00, Thurs., 8:30-2:00, Wed. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652
2010-09-24
/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656